#### § 111.375

### §111.375 Under this subpart K, what records must you make and keep?

- (a) You must make and keep records required under this subpart K in accordance with subpart P of this part.
- (b) You must make and keep records of the written procedures for manufacturing operations.

### Subpart L—Production and Process Control System: Requirements for Packaging and Labeling Operations

## §111.403 What are the requirements under this subpart L for written procedures?

You must establish and follow written procedures for packaging and labeling operations.

## §111.410 What requirements apply to packaging and labels?

- (a) You must take necessary actions to determine whether packaging for dietary supplements meets specifications so that the condition of the packaging will ensure the quality of your dietary supplements;
- (b) You must control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies. Label reconciliation is not required for cut or rolled labels if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations; and
- (c) You must examine, before packaging and labeling operations, packaging and labels for each batch of dietary supplement to determine whether the packaging and labels conform to the master manufacturing record; and
- (d) You must be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution.

# § 111.415 What requirements apply to filling, assembling, packaging, labeling, and related operations?

You must fill, assemble, package, label, and perform other related operations in a way that ensures the quality of the dietary supplement and that the dietary supplement is packaged

- and labeled as specified in the master manufacturing record. You must do this using any effective means, including the following:
- (a) Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary supplement packaging, as appropriate;
- (b) Protecting manufactured dietary supplements from contamination, particularly airborne contamination;
- (c) Using sanitary handling procedures;
- (d) Establishing physical or spatial separation of packaging and label operations from operations on other components and dietary supplements to prevent mixups;
- (e) Identifying, by any effective means, filled dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups:
- (f) Assigning a batch, lot, or control number to:
- (1) Each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement; and,
- (2) Each lot of dietary supplement, from a finished batch of dietary supplement, that you distribute to another person for packaging or labeling.
- (g) Examining a representative sample of each batch of the packaged and labeled dietary supplement to determine whether the dietary supplement meets specifications established in accordance with §111.70(g); and
- (h) Suitably disposing of labels and packaging for dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

## §111.420 What requirements apply to repackaging and relabeling?

- (a) You may repackage or relabel dietary supplements only after quality control personnel have approved such repackaging or relabeling.
- (b) You must examine a representative sample of each batch of repackaged or relabeled dietary supplements to determine whether the repackaged or relabeled dietary supplements meet all specifications established in accordance with §111.70(g).